alpha
THERAPEUTIC CORPORATION

15 July 1999

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Dockets Management Branch (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N–0583
Exports: Notification and Recordkeeping Requirements
Proposed Rule

Dear Sir:

Alpha Therapeutic Corporation is submitting the following comments regarding the proposed rule establishing the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

Enforcement and Penalties – The Food and Drug Administration (FDA) has not set forth the rationale for the requirements and the legal basis for its proposal. Generally such proposed requirements include a discussion of the relevant statutory provisions. The proposal does not provide that type of insight.

It is not clear that congress expected the FDA to impose a new record keeping and reporting requirements on industry. If the FDA plans to committ program time to receiving, reviewing, and following up on the notifications and export matters, there ought to be an explanation as to how the proposed requirements benefit the consumer, are important to fulfilling their role in enforcing the targeted sections of the Federal Food Drug and Cosmetic Act (FFDCA) and how and why congress placed this expectation on them. It is Alpha's understanding that the Export Amendments were designed to facilitate industry's ability to export unapproved products, which were acceptable in a foreign country, not create new burdens. The proposed notifications and record keeping requirements ostensibly appear to be unnecessary new burdens on industry.

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5555 Valley Boulevard, Los Angeles, California 90032-3520, USA • PHONE (323) 225-2221

Notification - FDA proposes that "simple" export notifications, regardless of whether they are to a "listed" or an "unlisted" country, identify both the product to be exported as well as the country to which the product is to be exported. The statute for the 1996 export law specifically indicates that for "listed" countries only the product need be identified. If FDA wishes to be notified of additional information in conjunction with exports to listed countries, it should either make that information discretionary for the notifying company or seek additional legislative authority. The proposed rule appears to be beyond the limits set in the statute. Under proposed 1.101(d), FDA would require that companies which export pursuant to 802(b)(1) to listed countries notify it of the name of the country even though the statute does not require it. Their rationale is that FDA must notify the health authority in the country if FDA does not approve the application for the unapproved product. That requirement seems unnecessary. If FDA disapproves a product application it will by virtue of 802(b)(1) know that exporting was occurring and they can request that information in any disapproval letter to the company. Having the information prior to such a decision seems unnecessary to FDA's effective implementation of their role under the statute.

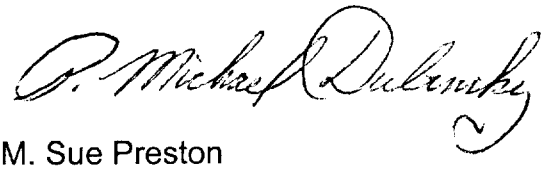
Five-year expiration date - The proposal is not clear as to the rationale and purpose for the five-year record keeping requirement. For example it is not explained how the timeframe fits with existing record retention requirements in current Good Manufacturing Practice Regulations or other rules. It seems possible that the five-year timeframe may be too long in some situations and not long enough in others. Absent a rationale and link to existing record retention requirements the five year proposal seems inappropriate and beyond the scope of the enabling legislation.

Recordkeeping - The recordkeeping requirements are excessive. Too many documents are being required to be kept for too long. FDA has attempted to particularize the statutory requirements for export by requiring documents that may not be required in order for an exporter to meet the statutory standard. By requiring that these types of records be kept as a legal requirement in order to demonstrate compliance with the export requirements, FDA has prompted a situation where an exporter can satisfy the statutory requirements for export but might be found in violation of the proposed regulations. For example, FDA lists detailed information that must be required in order for the agency to assure itself that the export meets the requirements of the foreign purchaser. Some foreign purchasers, however, may have extremely limited requirements, and may not require the detailed information of the type required by FDA in proposed 21 CFR1.101(b)(1).

The proposed regulation that the exporter must possess a copy of a document from the foreign country is not in the statute. A letter from a knowledgeable individual should be more than sufficient to satisfy this requirement.

In general, the Export Amendments were designed to facilitate industry's ability to export unapproved products which were acceptable in a foreign country. The proposed notifications and excessive recordkeeping requirements would create new burdens to industry. The FDA should withdraw the proposal and re-propose a more streamlined version that is in harmony with the statute.

Sincerely yours,



for M. Sue Preston
Vice President,
Quality and Regulatory Affairs

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